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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,079	08/06/2003	Janet K. Yamamoto	UF-152FWCD2	1433

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/636,079	YAMAMOTO, JANET K.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-107* is/are pending in the application.

4a) Of the above claim(s) *64-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-63* is/are rejected.

7)☒ Claim(s) *18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In the response filed June 17, 2004, Applicant's election of Group I (claims 18-63), with traverse, is acknowledged and entered. Claims 64-107 are withdrawn from consideration being drawn to non-elected inventions.

Claim Objections

2. Claim 18 is objected to for reciting the acronym, "FIV", which should be spelled out the first time it is recited.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vaccine for domestic cats comprising feline immunodeficiency virus (FIV) inactivated whole virus or inactivated FIV-infected cells comprising subtypes A and D, does not reasonably provide enablement for a vaccine for wild cats comprising all FIV-subtype immunogens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Claim 32 and all dependent claims recite "[A] vaccine composition that induces an immune response against two or more subtypes of FIV". While it is clear that a vaccine composition induces an immune response, vaccine compositions provide protection against infection and disease. *The Office has interpreted all claims that recite "vaccine" to include*

protection against FIV. If Applicant intends only to claim the induction of an immune response, then the composition should be called "immunogenic composition", not "vaccine".

The breadth of the claims encompasses a vaccine that protects against two or more subtypes of FIV. The vaccine comprises an FIV immunogen, or immunogens derived from or comprising at least two different FIV subtypes. Encompassed by the term "immunogen" is a viral vector FIV construct. The nature of the invention is the vaccination of domestic cats with FIV immunogens. The state of the art teaches that domestic cats are susceptible to FIV subtypes A-E, and wild cats are susceptible to subtypes Puma Pco and Lion Oma, see Figure 1 of Yamamoto *et al.* (*AIDScience*, April 26, 2002, 2(8)). The state of the art also teaches that inactivated whole viruses and inactivated FIV-infected cells comprising FIV subtypes A and D isolated from two long-term nonprogressor cats (Yamamoto *et al.*, page 3, last two paragraphs and Table 2) provide protection against FIV subtypes A, B and D. Individual subunit vaccine candidates and adenovirus-vectored FIV envelope protein did not result in protection, either homologous or heterologous (Yamamoto *et al.*, Table 2). The level of predictability in the art is low because it was unexpectedly discovered by Yamamoto *et al.* that subtypes A and D combined provide heterologous protection against A, D and B, while subtype A alone produces homologous protection. The amount of guidance provided in the specification for viral vector vaccines is limited to the mere mention of the idea, and is not supported by the instant inventor's own publication, Yamamoto *et al*, discussed above. Given the breadth of the claims, the state of the art, the lack of guidance and working examples in the specification, it would require undue experimentation to provide a vaccine comprising any immunogens other than those disclosed in Yamamoto *et al.*, or a viral vector vaccine. The specification only provides for protection

against subtypes A, B and D, by administering a vaccine comprising subtypes A and D. Therefore, the invention is not enabled commensurate in scope with the claims, which encompass a single immunogen subtype providing protection against two or more subtypes. In summary, in order for the claims to vaccines to be enabled, they should recite the type of animal that is susceptible to FIV (domestic cats), the specific subtypes that provide protection to those animals (A, D), the specific subtypes that are protected against (A, B and D), and the specific immunogens that confer protection (inactivated whole virus or inactivated FIV-infected cells).

4. Claims 18-30 and 44-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is apparent that interleukin-2 (IL-2) feline-derived T cells (claims 18-30), and (IL-2) feline-derived T cells having the identifying characteristics of the cells deposited as ATCC accession numbers CRL 11968, 11967, 11976, 11975, 10772 and 10775 (claims 44-49) are required to practice the claimed invention. The deposit of these cells is required because they are derivatives of deposited cells that have not been clearly identified by their "identifying characteristics". The structural components of the derived cells are not provided for in the specification. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112,

first paragraph, may be satisfied by a deposit of interleukin-2 (IL-2) feline-derived T cells (as recited in claims 18-30), and (IL-2) feline-derived T cells having the identifying characteristics of the cells deposited as ATCC accession numbers CRL 11968, 11967, 11976, 11975, 10772 and 10775 (as recited in claims 44-49). See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the above-mentioned IL-2 feline-derived T-cells or cells having their identifying characteristics, and it is not apparent if they are readily available to the public. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 18-63 recite "feline-derived", "derived" or "derived from". It is unclear what components are retained in the final product when they are derived from another product. Absent the structural identity of the final product, one would not know what elements are

retained. (Regarding the claim language of claim 38 and other claims reciting "a cell from one or more of the following", referring to deposited cell lines, the Office interprets the cell to be the exact cell of the deposit without any derivitization or alterations.)

- Claims 44-49 recite, "identifying characteristics". Lacking a definition of what exactly are the identifying characteristics of particular cell lines, one would not know what cells have the necessary characteristics.
- Claims 32-34, 38-49, 51-54 and 59-62 recite "partial FIV". It is unclear what structural components are required/retained in a partial FIV.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-23, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto *et al.* (*Intervirology*, 1991, 32:361-375, herein "Yamamoto"). The claims are drawn to an interleukin-2 (IL-2) independent feline-derived T cell which is susceptible to infection by FIV, wherein said cell does not require FIV infection for IL-2 independence. The cell is infected with an FIV virus, such as the *Petaluma* strain of FIV. The virus is inactivated and attenuated. Yamamoto discloses the development of two IL-2 independent feline lymphoid cell lines chronically infected with FIV. The cell lines contain the *Petaluma* strain of FIV (abstract and page 362, second column, first paragraph). The cell lines produce FIV, specifically, high levels

of viral core and envelope proteins (abstract). Inactivated whole-cell virus preparations were used for immunization (abstract). Therefore, the claims are anticipated by Yamamoto.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto as applied to claims 18-23 above, and further in view of Francis (WO 94/06471). The claim is drawn to an IL-2 independent feline-derived T-cell that expresses an FIV protein such as the envelope protein comprising SEQ ID NO: 1. Francis discloses the envelope sequence of the *Petaluma* strain of FIV in Figure 2, which contains Applicant's SEQ ID NO: 1 (see the attached sequence alignment). It would have been obvious to incorporate Francis' envelope sequence into the infected cell lines of Yamamoto because Yamamoto uses the same strain of FIV to infect cells. One would have had a reasonable expectation of success that the envelope protein of Francis would have infected in Yamamoto's cell line because Yamamoto's cells produced envelope proteins. Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,544,528. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a vaccine against FIV, and the patented claims are drawn to a vaccine against FIV. The patented claims recite a vaccine that comprises immunogens from a plurality of FIV subtypes. The instant claims recite a vaccine that comprises immunogens from at least two different FIV subtypes. It would have been obvious to make a vaccine having at least two different subtypes, since the patented claims are drawn to a vaccine that uses a plurality of subtypes. One would have had a reasonable expectation of success that the vaccine comprising at least two subtypes would have been successful because the patented vaccine (comprising a plurality) was successful.

9. Claims 18-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 6,605,282. Although

the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a genus of the patented species claims. The patented claims are drawn to a feline-derived T cell line having the identifying characteristics of the T cell line deposited under ATCC accession number CRL 11968 and 11967, and in some cases, the claimed cell line is the deposited cell line CRL 11968 or 11967. The instant claims are drawn to an IL-2 independent feline-derived T cell. The patented/deposited cell lines are also IL-2 independent. Therefore, it would have been obvious to make a cell line comprising an IL-2 independent feline-derived T cell because the patented species is drawn to a cell line(s) that is IL-2 independent. One would have had a reasonable expectation of success that the instant vaccine would have been successful because the patented vaccine comprising IL-2 independent T cells was successful.

10. Claims 27-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-63 of copending Application No. 10/408,701. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims are drawn to a species of the instantly claimed genus. The species claims are drawn to an IL-2 independent feline-derived T cell comprising an FIV which has been inactivated/attenuated in various ways (listed in claim 1 of the co-pending application). The genus claims are drawn to an IL-2 independent feline-derived T cell comprising an FIV that has been inactivated/attenuated.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SBC

Stacy B. Chen
August 17, 2004

JEFFREY STUCKER
PRIMARY EXAMINER

Sequence alignment of SEQ ID NO: 1 and Francis' (WO94/06471) Figure 2 (*Petaluma* envelope protein of FIV).

Database: geneseq

Date of search: June 10, 2004

```
RESULT 4
AAR51249
ID   AAR51249 standard; peptide; 856 AA.
XX
AC   AAR51249;
XX
DT   25-MAR-2003  (revised)
DT   08-OCT-1994  (first entry)
XX
DE   FIV PET-F14 envelope protein sequence.
XX
KW   Feline immunodeficiency virus; FIV; vaccine; diagnostic; AIDS;
KW   T-lymphotropic lentivirus; FIV UK8; FIV Petaluma; envelope protein.
XX
OS   Synthetic.
XX
FH   Key             Location/Qualifiers
FT   Peptide         1. .178
FT                   /note= "Hydrophobic leader peptide"
FT   Region          51. .66
FT                   /note= "V1 region"
FT   Region          95. .173
FT                   /note= "V2 region"
FT   Protein         179. .610
FT                   /note= "Surface glycoprotein"
FT   Region          360. .424
FT                   /note= "V3 region"
FT   Region          451. .483
FT                   /note= "V4 region"
FT   Region          539. .567
FT                   /note= "V5 region"
FT   Protein         611. .856
FT                   /note= "Transmembrane protein"
XX
PN   WO9406471-A1.
XX
PD   31-MAR-1994.
XX
PF   20-SEP-1993;   93WO-GB001974.
XX
PR   21-SEP-1992;   92GB-00019936.
XX
PA   (PITM ) PITMAN MOORE INC.
XX
PI   Francis MJ;
XX
DR   WPI; 1994-118168/14.
XX
PT   Feline immunodeficiency virus antigenic polypeptide(s) and nucleic acid -
PT   used to prepare prods. for combating or diagnosis of feline
PT   immunodeficiency infection.
XX
PS   Disclosure; Fig 2; 68pp; English.
XX
CC   The sequences given in AAR51248-R51262 and AAR58584-85 represent the
CC   feline immunodeficiency virus (FIV) envelope protein from different
CC   strains and serotypes. The consensus sequence basedon these, is given in
CC   AAR51247. The synthetic FIV peptides of the invention were derived
CC   principally from a combination of the sequences of the FIV UK 8 and
CC   Petaluma isolates, a composite sequence of which is given in AAR51246.
CC   Variations in the sequence may occur between different strains or
CC   serotypes, isolates of different geographical origin or even between
CC   different isolates from the same host. (Updated on 25-MAR-2003 to correct
CC   PN field.)
XX
SQ   Sequence 856 AA;

  Query Match             100.0%;  Score 136;  DB 2;  Length 856;
  Best Local Similarity   100.0%;  Pred. No. 2e-10;
  Matches   22;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 GSWFRAISSWKQRNRWEWRPDF 22
              ||||||||||||||||||||||
Db        385 GSWFRAISSWKQRNRWEWRPDF 406
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